OPTIMIZE Immunization systems and technologies for tomorrow

PATH World Health Organization

OVERVIEW

Stimulating innovation in the vaccine cold chain equipment industry

This document describes Optimize's effort to stimulate the development of two new categories of cold chain equipment—solar direct-drive refrigerators and passive-cooled cold boxes—by eliminating key market barriers and providing incentives to manufacturers to meet performance, quality, and safety specifications set by the World Health Organization (WHO).

Background

Vaccines are sensitive to both heat and cold, and they rely on temperature-controlled supply chains from the point of manufacture to the point of delivery. In most countries, this is achieved using cold rooms and refrigerators for storage and cold boxes or vaccine carriers filled with ice packs during transport. While the vaccine cold chain is generally functional in most countries, it is by no means optimal or easy, especially as bulkier and more expensive vaccines are introduced into vaccination programs.

In 2008, Optimize, a collaboration between WHO and PATH, conducted a landscape analysis of cold chain equipment to better anticipate what kind of technologies will be most needed in the vaccine cold chain over the next ten years.[1] Optimize then came up with a plan to stimulate the development of these new technologies to meet the demands of vaccine programs in low- and middle-income countries.[2,3]

Eliminating barriers to innovation

Although some cold chain equipment manufacturers may sell their equipment directly to countries, the majority of manufacturers strive to have their products prequalified by WHO, which enables them to reach a far larger market through the United Nations Children's Fund (UNICEF) procurement mechanism. To achieve WHO prequalification, manufacturers submit product dossiers and third-party test results to the Performance, Quality, and Safety (PQS) program at WHO showing they meet published specifications and test verification protocols for that specific type of equipment (e.g., refrigerators or cold boxes).

This system has been effective for maintaining a market for vaccine refrigerators, cold boxes, and vaccine carriers. However, it provides manufacturers little incentive to invest in research and development of cooling technologies that are not yet specified.

Working with the PQS program, Optimize helped create a pathway for innovative new cold chain technologies and helped WHO define new specifications for battery-free solar refrigerators as well as innovative vaccine carriers and cold boxes that can maintain longer cold life, carry more vaccines, and prevent freezing.

The next step was to engage manufacturers and convince them to design according to WHO's new specifications.

The Battery-Free Solar Refrigerator Challenge

Many health centers are located in areas with unreliable or no access to electricity. For years, these health centers used absorption refrigerators and freezers powered by bottled gas or kerosene. However, gas- and kerosene-powered refrigerators are now being phased out and solar photovoltaic refrigerators are the only prequalified alternative. Solar refrigerators can be highly reliable and effective, but they require an energy storage battery that needs to be imported and replaced every five years. Studies of solar refrigeration programs have shown that procuring, importing, and installing the replacement battery is difficult and can threaten the long-term viability of solar refrigerators.[4]

Solar vaccine refrigerators are the only prequalified refrigerator for locations with no access to electricity. Photo: WHO/Aya Kouamé

To address the battery problem, some refrigerator manufacturers began exploring a direct-drive solar refrigerator that does not require an energy storage battery. Instead, on cloudy days or at night, solar energy is stored in the form of ice or frozen liquid until solar energy can be generated again. To stimulate the market for direct-drive solar refrigerators, Optimize issued a battery-free solar refrigerator challenge in September 2008. The project invited refrigerator manufacturers around the world to submit designs for solar-powered refrigerators meeting the following specifications:

- The device meets the performance and safety standards of WHO PQS specification E03/RF05.01for battery-free solar refrigerators.[5]
- The device uses no batteries or other electrical storage component unless that component will have a 20-year service life (to match the PQS solar module warranty of 20 years).
- The device will operate under the conditions described in all three temperature zones as defined in the PQS specification.
- The device is designed to sell for less than US$3,000 per complete system, before shipping.

These specifications were indeed a challenge for manufacturers, and none of the final submissions met all four. The most important were the ability to meet the WHO PQS performance and safety standards and the ability to store cooling energy without the use of a large battery system.

Any products that met PQS specifications were offered free third-party product testing by a WHO-accredited laboratory, thus lowering the cost of accessing the UNICEF market. Further, when feasible, Optimize offered to include qualified technologies in demonstration projects in one or more countries, generating valuable field-monitoring data that could benefit the manufacturers.

The Cold Storage and Vaccine Carrier Challenge

Traditional cold boxes used for vaccine transport will generally stay cold for a maximum of about four days in ambient temperatures of around 30°C. Vaccine carriers used by health workers for campaigns and routine outreach sessions traditionally have a cold life of less than one day. A major challenge facing small, remote health facilities with limited access to equipment maintenance and repair services is to keep vaccines at proper temperatures for much longer periods of time during transport and storage without exposing vaccines to freezing temperatures.

In early 2009, Optimize challenged industry to submit designs or finished products for new cooling devices meeting the following specifications:

- The designs must prevent freezing temperatures in the vaccine compartment. Many vaccines are susceptible to freezing, and the traditional use of ice packs in these types of containers poses a risk to vaccines.[6]

Also, health workers often find it difficult to tell at a glance whether vaccine has been exposed to freezing temperatures.[7]

- A variety of vaccine capacity and cold-life combinations were specified.
  - A 3-liter mobile vaccine carrier for outreach efforts with a 3-day cold life.
  - A 3-liter stationary cold box for small facilities with a cold life of 30 days.
  - A 60-liter stationary cold box suitable for larger health centers, also with a cold life of 30 days.

All of these specifications stimulated manufacturers to design for longer cold life than has been traditionally available. If passive coolers are to play the role of a refrigerator in small health posts, they need to last a longer time between ice replacement or other recharge. Recognizing the significant technical challenge that a 30-day cold life represents, Optimize indicated that devices with a cold life of at least 7 days would be considered.

This long-life cold box was designed to keep vaccines cold for up to 7 days on one “charge” of ice. Photo: PATH/Nguyen Phu Cuong

Equipment evaluation

To evaluate the submissions in both challenges, Optimize convened review panels of international experts in vaccine cold chain technologies. Panel members were screened for any perceived conflicts of interest, each member signed a nondisclosure agreement, and each agreed to destroy all submitted material after review. To ensure objective review, Optimize staff removed information identifying the company behind each submittal. They evaluated the products based on how well they met the specifications and provided additional comments on the suitability of the devices for manufacture and for deployment to remote health centers in developing countries. They discussed their findings by teleconference.

These direct-drive solar refrigerators by The Solar Chill Company were field-tested in Senegal. Photo: PATH

Response from industry

For the refrigerator challenge, four companies based in the United States and Europe submitted device descriptions, including drawings and photographs, specifications, and internal test results. For the cold box/carrier challenge, two manufacturers submitted cold box dossiers. The relatively small response for the cold boxes may be attributable to the technical challenge of reaching a very long cold life and the uncertain market for these devices.

In the case of the solar refrigerators, three of the four products met PQS requirements during laboratory testing and were subsequently prequalified by WHO. Optimize also supported field-testing of two of these products in Senegal and Vietnam.

In the category of passive cooling devices, both submissions performed well during laboratory testing. Since WHO PQS standards are only recently published for these product category, prequalification has not yet been achieved (as of

July 2013). Field tests supported by Optimize were conducted in Senegal and Vietnam.

Conclusion

One objective of Optimize was to stimulate development of new cold chain technologies to meet the emerging needs of low-income countries. Optimize challenged industry to submit new battery-free solar refrigerators and passive cooling devices that met clearly defined product specifications. The project incentivized manufacturers by supporting product testing to facilitate regulatory approval as well as field-testing to demonstrate realistic use and publication of results. In the end, two manufacturers who had never produced equipment for the public health market in developing countries were motivated to participate, and one of them now has a vaccine refrigerator prequalified by WHO.

The industry challenges resulted in WHO prequalification of three new battery-free solar refrigerators. Two additional devices from competing manufacturers were submitted independently and accepted by PQS within the project term. In addition, two new passive cooling devices are poised for prequalification under WHO's new standards for this product category, published in December of 2012.[8]

FOR MORE INFORMATION

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